

rated by frangible seals and a side view of a plunger adapted for use with the housing, which are both components of a sample preparation and detection device according to the present disclosure.

[0035] FIG. 2B shows a cross-sectional view of the housing of FIG. 2A with a cap secured thereon and with a liquid sample disposed in an upper receptacle of the housing.

[0036] FIG. 2C shows a cross-sectional view of the housing of FIG. 2B without the cap and with a plunger disposed in a first position in the housing.

[0037] FIG. 2D shows a cross-sectional view of the device of FIG. 2C with the plunger disposed in a second position in the housing and the cell concentration agent transferred to the lower receptacle of the housing.

[0038] FIG. 3A shows a front view of one embodiment of a sample preparation and detection device comprising a housing and a valve, according to the present disclosure.

[0039] FIG. 3B shows a side view of the device of FIG. 3A.

[0040] FIG. 3C shows a cross-sectional view of the device of FIG. 3A with a liquid sample and a cell concentration agent disposed in an upper receptacle of the housing and the valve in a first position.

[0041] FIG. 3D shows a cross-sectional view of the device of FIG. 3C with the valve in a second position and the cell concentration agent transferred to the lower receptacle of the housing.

[0042] FIG. 4A shows a cross-sectional view of one embodiment of a housing comprising two receptacles and a drain valve and a side view of a plunger, which are both components of a sample preparation and detection device.

[0043] FIG. 4B shows a cross-sectional view of the assembled device of FIG. 4A with the drain valve in an open configuration and the plunger disposed in a first position in the housing.

[0044] FIG. 4C shows a cross-sectional view of the assembled device of FIG. 4B with the plunger disposed in a second position in the housing and the cell concentration agent transferred to the second receptacle of the housing.

[0045] FIG. 4D shows a cross-sectional view of the device of FIG. 4C, wherein the plunger has punctured the frangible seals and transferred the cell concentration agent to the lower receptacle.

[0046] FIG. 5A shows a cross-sectional view of one embodiment of a housing and a side view of a plunger, partially in section, which are both components of one embodiment of a sample preparation and detection device according to the present disclosure.

[0047] FIGS. 5B-5D show a cross-sectional views of the assembled device of FIG. 5A with the plunger inserted to various depths into the housing.

[0048] FIG. 6A shows an exploded side view, partially in section, of the tip of the plunger of FIG. 5A.

[0049] FIG. 6B shows a side view, partially in section, of the assembled tip of FIG. 6A.

[0050] FIG. 7A shows a cross-sectional view of one embodiment of a housing and a side view of a hollow plunger, partially in section, which are both components of one embodiment of a sample preparation and detection device according to the present disclosure.

[0051] FIGS. 7B-7D show a cross-sectional views of the assembled device of FIG. 7A with the plunger inserted to various depths into the housing.

[0052] FIG. 8A shows an exploded side view, partially in section, of the tip of the plunger of FIG. 7A.

[0053] FIG. 8B shows a side view, partially in section, of the assembled tip of FIG. 8A.

[0054] FIG. 9 shows one embodiment of a cell concentration agent collector according to the present disclosure.

[0055] FIG. 10A shows a cross-sectional view of one embodiment of a housing and a side view of a plunger, partially in section, which are both components of one embodiment of a sample preparation and detection device according to the present disclosure.

[0056] FIG. 10B shows a side view, partially in section, of the assembled device of FIG. 10A.

DETAILED DESCRIPTION

[0057] All patents, patent applications, government publications, government regulations, and literature references cited in this specification are hereby incorporated herein by reference in their entirety. In case of conflict, the present description, including definitions, will control.

[0058] The present invention generally relates to articles and methods for detecting microorganisms in a sample. In certain preferred embodiments, the present invention relates to the detection of live microorganisms in a sample. Methods and devices for the concentration of cells from a sample are described in U.S. Patent Application No. 61/141,900, filed Dec. 31, 2008 entitled "SAMPLING DEVICES AND METHODS FOR CONCENTRATING MICROORGANISMS" and U.S. Patent Application No. 61/141,813, filed Dec. 31, 2008 entitled "METHODS, KITS AND SYSTEMS FOR PROCESSING SAMPLES", each incorporated herein by reference in its entirety. The inventive devices and methods disclosed herein provide increased sensitivity to detect small numbers of microorganisms present in a sample.

[0059] Biological analytes can be used to detect the presence of biological material, such as live cells in a sample. Biological analytes can be detected by various reactions (e.g., binding reactions, catalytic reactions, and the like) in which they can participate.

[0060] Chemiluminescent reactions can be used in various forms to detect cells, such as bacterial cells, in fluids and in processed materials. In some embodiments of the present disclosure, a chemiluminescent reaction based on the reaction of adenosine triphosphate (ATP) with luciferin in the presence of the enzyme luciferase to produce light provides the chemical basis for the generation of a signal to detect a biological analyte, ATP. Since ATP is present in all living cells, including all microbial cells, this method can provide a rapid assay to obtain a quantitative or semiquantitative estimate of the number of living cells in a sample. Early discourses on the nature of the underlying reaction, the history of its discovery, and its general area of applicability, are provided by E. N. Harvey (1957), *A History of Luminescence: From the Earliest Times Until 1900*, Amer. Phil. Soc., Philadelphia, Pa.; and W. D. McElroy and B. L. Strehler (1949), *Arch. Biochem. Biophys.* 22:420-433.

[0061] ATP detection is a reliable means to detect bacteria and other microbial species because all such species contain some ATP. Chemical bond energy from ATP is utilized in the bioluminescent reaction that occurs in the tails of the firefly *Photinus pyralis*. The biochemical components of this reaction can be isolated free of ATP and subsequently used to detect ATP in other sources. The mechanism of this firefly